

### **REMARKS**

Favorable consideration of the subject application is respectfully requested in view of the above amendments and following remarks. This amendment and reply is responsive to the non-final Office action mailed July 25, 2008 and is being filed within one month following expiration of the three month shortened statutory period. A Petition for an Extension of Time of one Month and authorization for payment of the requisite fee accompany this filing.

Claims 1, 56 and 59 have been amended. Claims 1-7, 9, 10, 16-19, 24, 27-29, 32, 56 and 58-65 are pending in the application, with claims 1, 6, 18 and 56 being in independent format.

Claim 1 has been amended to incorporate subject matter previously recited in claim 59 and claim 59 has consequently been amended to delete dependence from claim 1. Claim 56 has been amended to additionally recite a guidewire brake selectable interrupt override control that, when actuated, permits an operator to rotate the operating head at low speed during withdrawal of the operating head from a material removal site of a patient. This feature is partially recited in dependent claim 57 and is described in the specification, as published, at paragraph 0063. Claim 57 has consequently been cancelled. The claims have not otherwise been amended.

It is submitted that the above amendments are fully supported by the specification as it was originally filed and that none of the amendments constitutes new matter.

### **Double Patenting Rejection**

Claims 1-5, 9, 10, 16, 17, 19, 24, 27 and 28 of this application were alleged to conflict with claims of co-pending U.S. Application No. 10/798,618. New independent claims were recently presented in the '618 application. It is submitted that the independent claims currently pending in these related applications maintain a clear line of demarcation between the applications and that the claims in the commonly owned, co-pending applications no longer conflict. Withdrawal of the double patenting rejection is requested.

### **Claim Rejections -- 35 USC § 103**

Claims 1 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (U.S. Patent 6,398,755) in view of Wulfman et al. U.S. Patent Publication US

2002/0007190 or Clement et al. U.S. Patent 6,565,588. This rejection is respectfully traversed in view of the following remarks.

Belef et al. discloses a catheter and catheter drive unit providing controlled translation of a rotatable catheter core with an operative element, e.g. an atherectomy cutter, at its distal end. Belef et al. do *not* disclose an operating head adjustable between two different operating diameters or a selection switch allowing an operating to select between two different operating head diameters, as noted by the Examiner. Wulfman et al. and Clement et al. disclose the use of an operating head adjustable between two different operating diameters similar to the operating head described in the present application.

Claim 1 has been amended to specify that the claimed control pod *additionally comprises control circuitry for inactivating power to the operating head when the current level required to maintain a desired rotational speed at the operating head exceeds a predetermined value*. This feature is recited in dependent claim 59, and Applicants do not perceive that this feature is disclosed or suggested in Belef et al. or Wulfman et al. or Clement et al., or that this feature would be obvious to one of ordinary skill in the art in light of any combination of teachings of these references.

Belef et al. disclose controls for starting and stopping the rotator and translator drives and (translation displacement) display reset capability. Belef et al. also disclose that the motor will be turned off when the catheter drive unit reaches the end of travel as sensed by a current sensor monitoring current to the motor, and that the motor will be automatically turned off if an obstruction is sensed, preventing or hindering movement of the unit along the drive track. (See, e.g., Col. 7, lines 33-42.) Wulfman et al. 2002/0007190 disclose an advanceable, rotating cutter assembly that may be implemented using certain automated and selectable control features. Clement et al. describes control systems for actuating, adjusting and providing system information concerning power, draft shaft rpm, drive shaft axial translation, aspiration, infusion and the like. None of the control features disclosed in the prior art teach or suggest the control circuitry specified in Applicants' pending claim 1, nor do any of the control features disclosed in the prior art references cited provide the combination of operability and safety provided in Applicants' claimed interventional catheter assembly. Applicants submit that claim 1, and the claims dependent therefrom, are in allowable form.

Claim 18 specifies that the drive motor, housed in the control pod, is coupled to *an actuator mounted on the catheter system distally to the control pod and in operable communication with the drive system, wherein the actuator incorporates a switch that activates at least one of the drive system and an aspiration system.* One embodiment of this actuator is illustrated in Fig. 3B; placement of the actuator on the catheter system distally of the control pod is illustrated in Fig. 1. The actuator and its operation are described in Applicants' specification, as published, at paragraphs 0064 and 0065.

The Examiner notes that Wulfman teaches a sliding actuator in communication with the drive system. Wulfman et al. disclose an advancer or tracking unit 14, which may incorporate adjustable controls and provide feedback data, and which provides an interface for an operator to translate the catheter assembly. This advancer or tracking unit 14 may house the drive motor and may provide many of the functions of the "control pod" recited in pending claim 18. Claim 18 specifies "an actuator mounted on the catheter system distally to the control pod," coupled to the drive motor and in operable communication with the drive system. Claim 18 additionally specifies that the actuator (mounted on the catheter system distally to the control pod) incorporates a switch that activates at least one of the drive system and an aspiration system. Applicants do not perceive that these features are disclosed in or suggested by any of the prior art references relied upon for rejection. Applicants also do not perceive that these features would be obvious to one of ordinary skill in the art in light of any combination of the teachings of any of the references relied upon for rejection, or the knowledge of one of ordinary skill in the art. Applicants submit that claim 18, and the claims dependent therefrom, are in allowable form.

Claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (U.S. Patent 6,398,755) in view of Grinberg et al. (U.S. Patent 5,921,956). This rejection is respectfully traversed in view of the following remarks.

Belef et al. disclose a catheter and catheter drive unit providing controlled translation of a rotatable catheter core with an operative element, e.g. an atherectomy cutter, at its distal end. The Examiner notes that Belef et al. fail to teach a torque selection feature and relies on Grinberg et al. for the teaching of a torque selection feature. Grinberg et al. disclose a common driver that may be used with a plurality of surgical instruments. The operation (e.g. speed, torque, direction of rotation) of the motor is controlled by a control unit. In particular, the speed of and torsion

applied by the motor may be controlled, depending on the type of instrument used, so that the speed and torsion applied by the motor doesn't exceed safe limits for that particular tool. (See, Col. 7, lines 49-62.)

Grinberg et al. reference a commonly assigned patent, U.S. Patent 4,705,038 with respect to speed and torque control techniques. The '038 patent discloses a single motor surgical system adapted to operate a set of different surgical devices having different operational limits. Each device has an indicator that denotes its operational limit. The sensor is adapted to limit the torque applied by the motor and limit the range of speed of the motor and is responsive to the indicator(s) to limit the voltage applied to the motor, while the motor is adapted to maintain its speed in accordance with the voltage applied. The sensor is responsive to limit the current applied to the motor to limit the torque delivered by the motor. (See, e.g., Col. 1, line 39 – Col. 2, line 1. Speed control is described in detail at Col. 5, starting at line 48; the torque limit setting is described in detail at Col. 6, starting at line 20.)

Pending claim 6 recites an interventional catheter assembly having, *inter alia*, a torque selection feature providing *operator selection of preselected torque levels delivered by the drive assembly to the drive shaft*. The selectable torque feature of applicants' system permits an operator to determine the torque delivered to the operating head separately from the rotational speed. This is useful, for example, when the interventional catheter is used to remove different types of lesions. Some lesions that are composed of hard material, for example, may require operation at a high torque setting, while other, softer lesions, may be removed using a lower torque setting, providing an additional level of safety. The interventional catheter recited in claim 6, thus, allows an operator to make a torque selection based upon the type and character of the lesion being removed. Applicants submit that this feature, and the flexibility it provides, is neither taught nor suggested by the prior art or any combination of prior art teachings. Applicants believe that claim 6, and the claims dependent therefrom, are in allowable form.

Claim 56 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of U.S. Patent 5,584,843 to Wulfsberg et al.. This rejection is respectfully traversed in view of the following remarks.

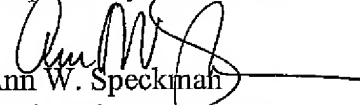
The teachings of Belef et al. are described above and, as noted by the Examiner, Belef et al. fail to teach a guidewire brake. The Wulfman et al. '843 patent, as well as other references cited by the Examiner, described a guidewire brake and certain guidewire brake control features. Claim 56 has been amended to specify that the catheter assembly additionally comprises *a guidewire brake selectable interrupt override control that, when actuated, permits an operator to rotate the operating head at low speed during withdrawal of the operating head from a material removal site of a patient.* Applicants do not perceive that this feature is disclosed in, or suggested by any of the prior art references cited by the Examiner and furthermore submit that this feature is not obvious in view of any combination of features, or teachings, of the prior art references relied upon for rejection. Applicants submit that claim 56, and the claims dependent therefrom, are in allowable form.

Claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32 and 58-65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of U.S. Patent 5,921,956 to Grinberg et al., U.S. 2002/0007190 to Wulfman et al., U.S. Patent 6,565,588 to Clement et al., and U.S. Patent 5,584,843 to Wulfman et al. Applicants believe that the pending independent claims are allowable in view of the prior art rejections stated above and submit that the dependent claims are therefore allowable as well.

***Conclusion***

In view of the above amendments and remarks, applicants believe that the pending claims 1-7, 9, 10, 16-19, 24, 27-29, 32, 56 and 58-65 are now in condition for allowance. Early consideration and allowance of all the pending claims are respectfully requested. The Examiner is invited to contact the undersigned if discussion of Applicants' pending claims, or the teachings of the prior art relied upon for rejection, would advance prosecution of Applicants' claims.

Respectfully submitted,

  
Ann W. Speckman  
Registration No. 31,881

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**SPECKMAN LAW GROUP PLLC**

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